UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-050
AAHRPP:	Element I.1.H.
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Updated By:	
Reviewed By:	IO; IRB(s); ORIO
Procedure Title:	Emergency Preparedness and Response Plan for Sustainability of the Human Research Protection Program

1.0 Objective

1.1. To describe the policies and procedures for initiating a response to an emergency situation impacting the Human Research Protection Program (HRPP) at the University of Southern Maine (USM).

2.0 Responsibility

2.1. It is the responsibility of the Institutional Official (IO), Office of Research Integrity and Outreach (ORIO), Research Compliance Administrator (RCA), and Institutional Review Board (IRB) to execute this SOP.

2.2. ORIO is responsible for evaluating this SOP and corresponding educational materials annually and making changes when appropriate in accordance with *HRPP-036 Standard Operating Procedures* and *HRPP-044 Quality Improvement/Quality Assessment*.

2.3. ORIO is responsible for posting this SOP and corresponding educational materials on its website for the human subject research community.

3.0 Limitations

3.1 The HRRP defers to the University of Maine System (system) and the University of Southern Maine (institution) emergency response planning.

3.2. This SOP is limited only to areas of HRPP authority under *HRPP-012 Authority of the Human Research Protection Program and Institutional Official* and not otherwise covered by system or institution plans.

3.3. This SOP establishes HRPP-specific planning and is intended to supplement, not replace, existing system and institution emergency response planning.

4.0 General Description

4.1. This SOP establishes the process to respond to an emergency that adversely impacts the HRPP.

4.2. Emergencies may include but are not limited to

4.2.1. Disease outbreaks, epidemics, or pandemics;

4.2.2. Extreme weather events;

4.2.3. Natural disasters;

4.2.4. Human-caused disasters;

4.2.5. Industrial accidents;

4.2.6. Infrastructure or cyber incursions;

4.2.7. Chemical, biological, radiologic, and nuclear threats.

4.3. This SOP is invoked only when the IO or designated individual, in accordance with *HRPP-012 Authority of the Human Research Protection Program and Institutional Official*, has indicated:

4.3.1. That an emergency has occurred or is imminent, and

4.3.2. The HRPP at USM is or is likely to be adversely impacted.

4.4. ORIO will coordinate with system and institutional officials in the development and implementation of training materials related to emergency preparedness and response plans specific to the HRPP.

4.5. New information, revised materials, and opportunities for continuing education are communicated to the USM human subject research community by way of various communication channels targeted to appropriate audiences to maintain awareness of IRB policies and procedures.

5.0 Procedure

5.1. The IO has indicated that an emergency has occurred or is imminent, and the HRPP is or is likely to be adversely impacted.

5.2. Assess the nature of the emergency event and the appropriate response.

5.2.1. Consult existing HRPP SOPs and any system or institution emergency preparedness plans or information already in place.

5.2.1.1. Proceed in accordance with those plans and determine whether further contact or notification of the human subject research community is necessary.

5.2.2. Work with the IO to notify the human subject research community of the emergency and its impact on the HRPP.

5.2.2.1. Communications will occur via routine shared communication routes such as email and websites.

5.2.2.1.1. If the emergency affects routine communications, identify alternative communication strategies such as radio, direct text messaging, or social media platforms.

5.2.2.2. Target communications and education will be developed and distributed based on the specific emergency and distinct responsibilities of the human subject research community member.

5.2.2.2.1. Communications will include instruction, education, and expectations for impacted human subject research community members.

5.2.3. When the emergency no longer presents an adverse impact on the HRPP, work with the IO to notify the human subject research community that normal HRPP function has resumed.

5.3. Assess whether the emergency may impact HRPP operations.

5.3.1. Work with the IO to notify the human subject research community of the impact on HRPP operations.

5.3.2. If the impact on HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.

5.3.2.1. If reliance on one or more external IRBs is required, identify appropriate candidates for external IRB reliance and follow *HRPP-028 IRB Reliance*.

5.3.3. If the emergency will prevent any upcoming IRB meetings from properly convening in person and an in person meeting was planned, determine whether the meeting can be conducted virtually.

5.3.3.1. If a virtual meeting is feasible, arrange for a virtual meeting and follow *HRPP-009 Conduct of IRB Meetings*.

5.3.3.2. If a virtual meeting is also not feasible, determine whether to cancel or reschedule the meeting.

5.3.3.2.1. If canceling or rescheduling a meeting causes currently IRB-approved studies to have approvals lapse, the investigators will be notified and instructed to cease all study-related activities that are not necessary for subject safety upon approval expiration and will be instructed to follow *HRPP-030 Continuing Review*.

5.3.4. If ORIO or the IRB will be unable to complete their protocol processing and review responsibilities during the emergency, determine any alternative capacity available for protocol processing and reviews.

5.3.4.1. Prioritize protocol processing and reviews.

5.3.4.1.1. Considerations may include, but are not limited to, approved studies that may expire while the emergency presents limitations, studies that may include interventions that may harm participants if discontinued, and studies involving direct interactions or interventions that can continue via alternative mechanisms such as remote access.

5.3.4.2. Make allowances for alternative methods for protocol processing and review, including but not limited to paper-based systems, accepting submissions prior to impending emergencies, utilizing remote access, delaying protocol review, postponing new submissions, or reassigning reviews to IRB members who are still able to perform the functions.

5.3.4.3. If data or records are unavailable during the emergency, consult with system or institution Information Technology support and any electronic system vendors to implement alternative procedures to access the data.

5.3.4.3.1. If capacity limitations on protocol processing and review responsibilities cause currently IRB-approved studies to have approvals lapse, the investigators will be notified and instructed to cease all study-related activities that are not necessary for subject safety upon approval expiration and will be instructed to follow *HRPP-030 Continuing Review*.

5.4. Assess whether the emergency may impact the ability of investigators to conduct human subject research.

5.4.1. Work with the IO to notify the human subject research community of the impact on investigators.

5.4.2. Determine whether the emergency necessitates additional flexibility in HRPP policies or procedures.

5.4.2.1. Consult with the IO to develop short-term procedures for investigators to carry out or suspend human subject research.

5.4.2.2. Triage the types of research that may continue and the types of research that may need to be temporarily postponed.

5.4.2.2.1. Considerations may include but are not limited to, studies that present a likelihood of direct benefit to participants, studies that may include study interventions that may harm participants if discontinued, studies involving direct interactions or interventions that can continue via alternative mechanisms such as remote access, and studies that may have an adverse impact on the resources required to address the emergency.

5.4.2.3. Examine the need for protocol-specific emergency mitigation plans.

5.4.2.3.1. If studies involve in-person interactions with research participants, determine whether the studies may be conducted as written while adhering to any emergency mitigation plans.

5.4.2.3.2. As part of a mitigation plan, work with investigators to implement mitigation strategies such as but not limited to, alternative or backup maintenance of data or specimens, suspending recruitment or enrollment, online or remote methods for research procedures, use of waivers of documentation of consent, or reliance on an external IRB.

5.4.2.3.3. When studies have an external sponsor, ensure coordination with the sponsor to confirm emergency mitigation plans.

5.4.2.3.4. If the emergency could impact clinical care standards, which could, in turn, impact research, work with investigators to clarify what does and does not require IRB review.

5.4.2.3.5. If research participants are unable to visit an investigational site for protocol-specified visits, evaluate alternative methods for safety assessments.

5.5. Assess whether the emergency may pose additional threats or risks to specific aspects of the institution's research activities or facilities.

5.5.1. If broader system or institution-level emergency preparedness plans do not already address these specific activities or facilities, work with the IO and appropriate leadership to escalate and address any additional threats or risks.

6.0 References

6.1. AAHRPP Tip Sheet: Emergency Preparedness and Response
6.2. University of Southern Maine Emergency Action Plan
6.3. University of Maine System Safety Management Department
6.4. University of Maine System Hazard Mitigation Plan
6.5. University of Maine System Emergency Action Plans Policy